**REMARKS**

Claims 25 and 27-39 are pending. Claims 25 and 27-35 have been amended. New claims 36-39 have been added. Applicant notes that the error in the numbering of the claims has been corrected. As the Examiner rightly noted in the Office Action, claim 33 was missing.

Applicant has amended claims 27-34 to accommodate the amendments to claim 25; that is, the amendment from "pharmaceutical product" to "pharmaceutical composition." No new matter has been added by way of this amendment.

Support for the amendments to claims 25, 35, and for new claim 36 may be found at least on page 25, lines 8-12 where the notion of a composition comprising "one or more encapsulated products" is introduced. Applicant submits that, since this section of the specification makes reference to a composition that comprises more than one encapsulated product, this section provides adequate support for the term "a plurality of encapsulated products" that is recited in claims 25 and 36 and for the term "a plurality of venlafaxine-containing caplets" recited in claim 35. Support for claim 36 may also be found at least on page 26 (Example 1; substituting venlafaxine for dimenhydrinate) and on page 8, lines 21-22 of the specification, where venlefaxine is specifically disclosed. Support for "the pharmaceutical composition provides controlled release of venlafaxine HCl" may be found on page 19, lines 22-26.Accordingly, no new matter has been introduced by way of the amendments to claims 25 and 35 or the addition of claim 36.

Support for "carbohydrate in claims 25, 35, and 36 and for new claims 37-39 may be found at least at page 18, lines 1-5. Accordingly, now new matter has been added by way of the new claims.

I. *The rejection under 35 U.S.C. § 112, first paragraph should be withdrawn*

Claims 25, 27-29, and 31-35 stand rejected under 35 U.S.C. § 112, first paragraph for the reasons set forth on page 2 of the Office Action as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that "[t]he specification as originally filed does not envision diameters in the range of about 1 millimeter to about 3 millimeters" and that the addition of a 1-3 mm range for the diameter constitutes new matter. Applicant respectfully disagrees.

Applicant offers that the description of the invention discloses encapsulated products (*e.g.*, caplets) having diameters within the range of 1 to 7 mm, as well as specific embodiments of encapsulated products (*e.g.*, caplets) having 3 mm in length and 3 mm in diameter (see Example 1) and of encapsulated products (*e.g.*, caplets) having 1.3 mm in length and 1.3 mm in diameter (see Example 1). As a factual matter, therefore, persons skilled in the art would consider encapsulated products (*e.g.*, caplets) having a diameter "from about 1 millimeter to about 3 millimeters and a length from about 1 millimeter to about 3 millimeters" to be part of Applicant's invention.

This factual scenario is very similar to the factual scenario in *In re Wertheim et al.*, 541 F.2d 257 (C.C.P.A. 1976); that is, Applicant discloses a broad range (1-7 mm) and points within that range (1 mm, 1.3 mm, and 3 mm). Similarly, in *Wertheim* appellant disclosed solids contents in freeze-dried instant coffee within the range of 25-60% along with specific embodiments of 36% and 50%. The court in *Wertheim* held that a broad range (25-60%) and points within that range (36% and 50%) satisfied the written description requirement for a range of 35-60% solids content—a range that lacked verbatim support in appellant's disclosure. Never the less, the court in *Wertheim* held that "as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants' invention." *Id.* In short, the court in *Wertheim* echoed the holding in *Lukach* that "the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of § 112." As in *Wertheim*, the Examiner in the instant case should realize that a broad range (1-7 mm) and points within that range (1 mm, 1.3 mm, and 3 mm) provide ample written description for the claimed range of about 1 millimeter to about 3 millimeters for the diameter and from about 1 millimeter to about 3 millimeters for the length. Applicant asserts, therefore, that claims 25 and 35, and the claims that depend therefrom, comply with 35 U.S.C. § 112, first paragraph at least for the foregoing reasons. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicant reiterates that the Patent Office has done nothing more than to argue lack of literal support, which is not enough. *See*, *In re Wertheim et al.*, 541 F.2d 257, 265 (C.C.P.A. 1976) citing *In re Lukach*, 442 F.2d 967, 969 (C.C.P.A. 1971). If lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach* that "the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of § 112," is empty verbiage. *Id.*

Claim 25 has also been rejected under 35 U.S.C. § 112, first paragraph for the reasons set forth on page 4 of the Office Action as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the specification does not envision generic polyvinylpyrrolidone. Applicant points out that this rejection is now moot in light of the amendments to claim 25. Reconsideration and withdrawal of the rejection are respectfully requested.

II. *The rejection under 35 U.S.C. § 103(a) should be withdrawn*

Claims 25, 27-32, 34, and 35 stand rejected over U.S. Patent No. 6,197,828 to Jerussi *et al.* Claims 25 and 33 also stand rejected over Jerussi in view of US2002/0015731 to Appel *et al.*, or U.S. Patent No. 6,306,436 to Chungi *et al.* Applicant respectfully traverses these rejections.

Claim 25, is drawn to a pharmaceutical composition comprising a plurality of encapsulated products. The plurality of encapsulated products provide a therapeutically effective amount of venlafaxine HCl. Each encapsulated product comprises venlafaxine HCl; at least one compressible material; and at least one lubricating material. In addition, each encapsulated product is processed using a tableting machine; and has a diameter from about 1 millimeter to about 3 millimeters and a length from about 1 millimeter to about 3 millimeters. Lastly, the pharmaceutical composition provides controlled release of venlafaxine HCl.

Claim 35, on the other hand, is drawn to a pharmaceutical composition comprising a plurality of venlafaxine-containing caplets wherein the plurality of caplets provide a therapeutically-effective amount of venlafaxine. Each caplet is made by compressing a mixture comprising venlafaxine-containing granules and at least one lubricating material. The granules comprise venlafaxine; and at least one compressible material. The pharmaceutical composition provides controlled release of venlafaxine HCl; and each caplet has a diameter from about 1 millimeter to about 3 millimeters and a length from about 1 millimeter to about 3 millimeters.

Claims 25 and 35, from which all of the dependent claims depend, are directed to a pharmaceutical composition comprising a plurality of either encapsulated products or caplets. It is worth noting that a single encapsulated product or caplet contained in the claimed pharmaceutical compositions does not deliver the therapeutically effective amount of venlafaxine. Instead, the entire plurality of encapsulated products or caplets delivers the

therapeutically-effective amount of venlafaxine. In other words, each encapsulated product or caplet only comprises a fraction of the total therapeutically effective amount of venlafaxine.

Applicant offers that none of the references cited by the Examiner to date, including Jerussi, alone or in combination with Appel or Chungi, teach, suggest, or otherwise contemplate the claimed pharmaceutical composition comprising a plurality of either encapsulated products or caplets. Instead, Jerussi teaches a formulation that appears to be a powder strictly suited for dry-filling into a hard gelatin capsule. Further, Jerussi teaches that all of the venlafaxine required to produce a therapeutically effective dosage is contained in the powder that is filled into the hard gelatin capsule dosage form (see Table II, column 26). In other words, Jerussi does not teach individual encapsulated products or caplets contained in a capsule, where each encapsulated product or caplet comprises a fraction of the venlafaxine required to produce a therapeutically effective dosage. Also, Jerussi does not appear to have any teaching of using a granulation, let alone granules that are mixed with a lubricant and subsequently pressed into a caplet, as claimed in claim 35. Neither Appel nor Chungi appear to remedy any of the aforementioned deficiencies in Jerussi.

In addition, Jerussi, alone or in combination with Appel or Chungi, fails to teach, suggest, or otherwise contemplate encapsulated products or caplets of the claimed size—a size that makes them suitable for, *e.g.*, filling into a hard gelatin capsule, and that imparts the unique properties upon the presently claimed encapsulated products or caplets.

Finally, Jerussi, alone or in combination with Appel or Chungi, fails to teach, suggest, or otherwise contemplate the controlled release of venlafaxine, particularly using a formulation containing no controlled release excipients. In a response to the September 30, 2005 Office Action, Applicant presented evidence in the form of a Declaration under 37 C.F.R. § 1.132 showing the controlled release of venlafaxine with the claimed encapsulated product/caplet—even though it contains no controlled release excipients. *See* APPENDIX C to the Declaration. In contrast, Jerussi's formulation, even when modified by Applicant[1] so that it would tablet and in

[1] It took Applicant a fair amount of experimentation to eventually modify Jerussi's formulation sufficiently to form a tablet. Even though Jerussi does not teach granulation, Applicant used materials that are, in fact, disclosed by Jerussi to modify Jerussi's formulation so that it would tablet. For example, Jerussi teaches the use of talc as a filler or as a lubricant. *See* Jerussi at 18:17-22 and 18:51-59. In other words, Applicant used only Jerussi's disclosure to modify

(continued...)

the form of a tablet having a larger dimension than the claimed encapsulated products or caplets, immediately releases (*i.e.*, within 15 minutes) the venlefaxine.

In sum, none of the references cited by the Examiner to date, including Jerussi, alone or in combination with Appel or Chungi, teach, suggest, or otherwise contemplate the claimed invention. Accordingly, Applicant requests the reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

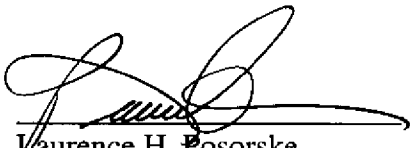
## CONCLUSION

Entry of the foregoing and prompt and favorable consideration of the subject application on the merits are respectfully requested. Applicant respectfully submits that the pending claims are in condition for allowance.

Respectfully submitted,

Hunton & Williams LLP

Date: February 19, 2009

By: 

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Jerussi's formulation so that it would tablet. Even after modifying Jerussi's formulation so that it would tablet, Applicant observed that such a tablet behaved significantly differently than the claimed encapsulated products or caplets.